

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 25, 2017

Jesse Evans Regulatory Affairs Supervisor Perrigo Company 515 Eastern Ave. Allegan, MI 49010

Subject: Label Amendment – Removal of broadcast language from the label.

Product Name: 0.5% Permethrin Aerosol Spray

EPA Registration Number: 71-1 Application Date: January 9, 2017

Decision Number: 525796

Dear Mr. Evans:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

Gene Benbow, Acting Product Manager 4

Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

Su to

Office of Pesticide Programs

- Bedding spray [lice treatment]
- For bedding and furniture
 - OR For use on bedding
 - OR For use on bedding, furniture and other inanimate objects infested with lice
 - OR Home lice control spray [for bedding and furniture]
- Kills lice [and their eggs] on mattresses OR [bedding], furniture, car interiors [and] other nonwashable items
- [Spray] Kills lice, bedbugs & dust mites on bedding, mattresses, furniture and car interiors
- Kills lice [and their eggs]
- [Spray] Lice treatment [kills lice] OR Lice treatment- for use on bedding [& furniture]
- [Lice] [bed][[ding]] spray
- In-home [lice control spray] OR [In-] Home lice, [&] bedbug [& dust mite] spray
- Lice [control OR treatment]
- Shake well before using
- [Step 3:] [of] 1-2-3 lice control system

OR Stop lice step 3

OR [Step] 3 [: Spray]

OR 3 Control

OR Step 3 [clear]

OR [Step 3] Home lice, bed bug & dust mite spray

- Questions? 1-800-XXX-XXXX
 - OR Questions or comments: 1-800-XXX-XXXX
 - OR For comments or questions please call 1-800-XXX-XXXX
- Aviso al consumidor: si no sabe inglés, pídale a alguien que le lea toda la información que aparece en el empaque antes de utilizar este producto.
 - Notice to consumer: If you are unable to read English, please have someone read the full packaging label to you before using this product.
- Not for use on humans [or animals]
- Spray kills lice & bedbugs on bedding & furniture

ACCEPTED

04/25/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 71-1

- Kills bed bugs
- Controls listed residential and garden insects
- For treatment of clothing, nets, sleeping bags & backpacks
- Kills & repels mosquitoes and ticks
- Controls ticks that can cause Lyme disease
- Repels ticks that can cause Lyme disease
- One clothing [fabric] treatment lasts 2 weeks [!]
- A water based aerosol
- [Kills house] [Helps control] dust mites in carpets, curtains and on upholstery
- [Controls house] [Helps control] dust mites (Dermatophogoides spp.) for up to 8 weeks [2 months,
 60/days] in carpets, curtains and on upholstery
- [Controls house] [Helps control] dust mites that may cause asthma, hay fever, rhinitis, wateryeyes, sneezing
- For bedding and furniture this product [product name] is effective in the control of dust mites
- Kills carpet beetles
- Kills ants
- Kills: houseflies, fruit flies, mosquitoes, gnats, black flies, skipper flies, blow flies, lady bugs [beetles] and small flying moths
- Kills: cockroaches, waterbugs, palmetto bugs, silverfish, firebrats, crickets, scorpions, spiders,
 millipedes, centipedes, sowbugs and pillbugs
- Read entire label before [each] use

[[HOME] LICE, BEDBUG & DUST MITE SPRAY]

[Not for use on humans]

[This product is Step 3 of a three step lice control system [that includes a shampoo as Step 1 and a combing gel as Step 2].

[Step 1: Kill lice with [product name]. Re-apply in 10 days.]

[Step 2: Comb out eggs & nits with [insert product name].]

[Step 3: Clean home. Use this product [OR product name] for non-washable items.

Washables should be washed in hot water and dried in high heat.]

ACTIVE INGREDIENT:

OTHER INGREDIENTS**:.....99.50%

100.00%

*Cis/trans ratio: Max. 55%(+/-) cis and Min. 45% (+/-)trans.

**Contains petroleum distillate.

KEEP OUT OF REACH OF CHILDREN CAUTION[:]

See Back Panel for Additional Precautions

Aviso al consumidor: si no sabe inglés, pídale a alguien que le lea toda la información que aparece en el empaque antes de utilizar este producto.

Notice to consumer: If you are unable to read English, please have someone read the full packaging label to you before using this product.

EPA Reg. No. 71-1

EPA Est. No. See Bottom or Top of Can

FIRST AID	
If an akin a Take off contonsingted alothing	
If on skin	Take off contaminated clothing.
or	 Rinse skin immediately with plenty of water for 15-20 minutes.
clothing:	 Call a poison control center or doctor for treatment advice.
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes.
_	 Remove contact lenses, if present, after the first 5 minutes, then continue rinsing
	eye.
	Call a poison control center or doctor for treatment advice.
If	Immediately call a poison control center or doctor.
swallowed:	 Do not induce vomiting unless told to do so by a poison control center or doctor.
	Do not give any liquid to the person.
	Do not give anything by mouth to an unconscious person.
If inhaled:	Move person to fresh air.
	 If person is not breathing, call 911 or an ambulance, then give artificial
	respiration, preferably by mouth-to-mouth, if possible.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or	
going for treatment. For additional information on this product (including health concerns, medical	
emergencies or pesticide incidents), you may call X-XXX-XXXX.	
NOTE TO DUVE CLAN	

NOTE TO PHYSICIAN

Contains petroleum distillate – vomiting may cause aspiration pneumonia.

NET CONTENTS: [NET Weight: #oz. (#g)]

PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals

CAUTION: Harmful if absorbed through skin. Avoid inhalation of spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or the toilet. Remove and wash contaminated clothing before reuse.

[Products used exclusively indoors may omit the Environmental Hazards Statement.]

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwater or rinsate. See Directions for Use for additional precautions and requirements.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are foraging the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use Restrictions:

- [[Except when applying to clothing,] Do not allow adults, children, or pets to enter until
 vapors, mists and aerosols have dispersed, and the treated area has been thoroughly
 ventilated.]
- [Except when applying to clothing,] Do not allow adults, children, or pets to enter the treated area until sprays have dried.
- In the home, cover all food processing surfaces and utensils during treatment and thoroughly wash before use. Cover or remove exposed food.
- Remove pets, birds and cover any water inhabited by fish (such as aquariums and ornamental fish ponds) before application. Turn off aquarium filtering systems before spraying and wait approximately 15 minutes after application before turning the filter back on.
- This product is not for use on humans. If lice infestations should occur on humans, use a product labeled for use on humans.

- Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur.
 Do not allow the product to enter any drain during or after application.
- Not for broadcast use on indoor residential surfaces.

[Products used exclusively indoors may omit the following restrictions:]

- All outdoor applications must be limited to spot or crack-and-crevice treatment only except for the following permitted uses:
 - 1. Treatment to soil or vegetation around structures
 - 2. Applications to lawns, turf and other vegetation
 - 3. Applications to building foundations up to a maximum height of 3 feet Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors and eaves) are limited to spot and crack-and-crevice applications only.
- Do not water the treated area to the point of run-off.
- Don not make applications during rain.

[We recommend that those with asthma or severe allergies consult their doctor before using this product and have someone else apply this product.]

SHAKE WELL BEFORE USING

Remove protective cap. Hold container upright [with nozzle away from you.] [Depress valve] and spray from a distance of 12 to 15 inches for baseboards, moldings and when applying to floors as a spot spray and 8 to 10 inches for clothing, furniture and bedding. Test product on an inconspicuous area before applying [to check for possible staining or discoloration]. [Inspect again after drying.] [Spray until surface is slightly wet, but not to the point of run-off.] OR [Spray to the point of dampness but not run-off.] Over application may cause damage. Will not stain surfaces or fabrics where water alone causes no damage.

To kill *Lice* and *Louse eggs:* [Clean home.] Use this product for non-washable items only. Washables should be washed in hot water and dried in high heat. Spray only those articles and parts of bedding, including mattresses and furniture that cannot be either laundered or dry-cleaned. Do not use on sheets or pillowcases. Allow all sprayed articles to dry thoroughly before use. [If lice infestation occurs on humans, use a product labeled for use on humans.]

Bedbugs: Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all joints. Treat baseboards, moldings and floors. Spray to the point of dampness but not run-of. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Retreat if infestation occurs, but not more than once every two weeks.

To control [Kill] [Helps Control] House Dust Mites (Dermatophagoides spp.): This product [OR product name] controls [helps control] house dust mites that may cause asthma, hay fever, rhinitis, watery eyes and sneezing. One treatment lasts for up to 8 weeks [2 months, 60 days]. On Upholstered Furniture – test fabric in an inconspicuous area to insure dyes will not bleed. [Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches.] Spray all fabric surfaces until damp. [Spray to the point of dampness but not run-off.] Do not use on delicate fabrics. Allow furniture to dry thoroughly before using. **On Carpets-** Apply as a spot spray to areas where dust mites are likely [including along baseboards and moldings]. [Hold nozzle approximately 12 to 18 inches from the carpet surface.] Spray until damp. After application, brush the surface of the carpet with a broom or brush to insure deep penetration. Allow carpet to dry thoroughly [before reentering the treated area]. [Drying time can be accelerated by using a fan.] On Mattresses- Spray the top, bottom and sides of mattresses until damp, paying particular attention to tufts and seams. Allow to dry thoroughly before using. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Vacuum entire area once dry. Since vacuuming stirs dust up in the air those with allergies should have another person vacuum or should wear a dust mask and use vacuum with a high efficiency particulate (HEPA) filter.

Carpet Beetles: Spray directly on beetles, floors, baseboards, shelves, and carpets as a spot treatment. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

As a space spray for *Houseflies, Fruit Flies, Mosquitoes, Gnats, Black Flies, Skipper Flies, Blow Flies* and *Small Flying Moths:* Close all doors and windows and spray room at the rate of 2 to 3 seconds per 1000 cubic feet. Direct spray to all parts of the room, especially windows and other light sources, which attract these insects. Keep nozzle in constant motion. Retreat if infestation occurs, but not more than once every two weeks.

Cockroaches, Waterbugs, Palmetto Bugs, Silverfish, Firebrats, Crickets, Scorpions, Spiders, Millipedes, Centipedes, Sowbugs and Pillbugs: Spray into hiding places such as cracks and crevices, behind sinks, cabinets, along baseboards and floors, around drains and plumbing, hitting insects with spray whenever possible. When applying to floors, apply as a spot treatment. Spray to the point of dampness but not run- off. Retreat if infestation occurs, but not more than once every two weeks.

Ants: Spray trails, nests and points of entry. Spray on ants where possible. Retreat if infestation occurs, but not more than once every two weeks.

As a space spray for *Indian Meal Moths, Angoumois Grain Moths:* Close doors and windows, direct spray into all parts of room especially around stored food product containers, pallets and darkened areas. Spray 7 to 10 seconds for each 1000 cubic feet of space. Keep area closed for 15 minutes following treatment. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

TO CONTROL *Clothes Moths* and *Carpet Beetles* on wool and other proteinaceous fibers: Remove infested articles from storage, brush thoroughly, and air for several hours in sunlight, if possible. Apply spray liberally to empty chests, closets, bureaus and other storages directing the spray into cracks, joints and crevices. Spray to the point of dampness but not run-off. After airing, infested articles may be treated by spraying lightly, keeping nozzle at least three feet from fabric to avoid staining.

CLOTHING TREATMENT

Clothing treatment only – do not apply to skin.

For protection against *Ticks* (including those which may carry Lyme disease) and *Mosquitoes*, apply product as directed below. For further protection, use in conjunction with an insect repellent registered for direct application to the skin and utilize the following primary preventive measures. Avoid areas where the pests are found, wear appropriate protective clothing (light-colored, long-sleeved shirt and long pants tucked into socks) and inspect body daily for ticks. Pant cuffs should be worn inside the socks or footwear to ensure full protection against ticks.

Initial Treatment Instructions:

- 1. Select a well-ventilated outdoor area protected from wind and lay out the clothing to be treated (as complete outfit; shirt, trousers and socks).
- 2. Hold can upright about 6 to 8 inches from surface of the clothing and spray with a slow sweeping motion to lightly moisten the surface of the fabric.
- 3. Continue spraying over entire outfit, until a total treatment time of 60 seconds has elapsed and the outer surface of the fabric is moist enough to cause a slight color change or darkening. Pay special attention to socks, trouser cuffs and shirt cuffs.
- 4. Turn the clothing over and treat the other side as described in Steps 2 & 3.
- 5. Hang the treated clothing and allow to dry for at least 2 hours (4 hours under humid conditions) before wearing.
- 6. One [# oz] can will treat [two] complete outfit(s). Do not exceed labeled spraying times.

Retreatment Instructions:

The product contains an active ingredient which actually binds to the fabric being treated, providing residual protection which lasts a minimum of two weeks, and hold up through several machine washings. DO NOT RETREAT CLOTHING MORE THAN ONCE EVERY TWO WEEKS. LAUNDER CLOTHING AT LEAST ONCE BEFORE RETREATING. For retreatment, follow instructions for initial treatment.

TREATMENT OF NETS, TENTS, SLEEPING BAGS AND BACKPACKS:

Initial Treatment Instructions: Do not treat inside of sleeping bag. Spray exterior surfaces of tent only. Select a well-ventilated outdoor area protected from wind and lay out article to be treated. Hold can upright about 6 to 8 inches from surface of the article and spray with a slow sweeping motion to lightly moisten the surface of the fabric. Continue spraying over entire article, until the outer surface of the article is moist enough to cause a light color change or darkening. Turn the article over and treat the other side as described in steps 2 and 3 above for clothing treatment. Hang the treated article and allow to dry for at least 2 hours (4 hours under humid conditions) before using.

Retreatment Instructions:

The product contains an active ingredient which actually binds to the fabric being treated, providing residual protection which lasts a minimum of two weeks, and hold up through several machine washings. DO NOT RETREAT CLOTHING MORE THAN ONCE EVERY TWO WEEKS. For retreatment, follow instructions for initial treatment.

FOR THE CONTROL OF GARDEN INSECTS: For use on roses, dahlias, asters and other ornamentals to kill *Japanese Beetles* hit by spray, as well as *Whiteflies, Aphids, Exposed Thrips, Spider Mites, Red Mites* and *Leafminers*.

May be used on plants, as well as a multi-purpose spray in small gardens and for spot treatments of incipient insect infestations to prevent spreading in large garden areas.

May also be used on other plants such as African violets, azaleas, begonias, camellias, carnations, chrysanthemums, delphiniums, dogwood, English ivy, euonymus, fuschia, geraniums, crassula, grape vine, Kentia palm, laurel, marigolds, rhododendrons, rubber plants, snapdragons, stocks, wandering Jews and zinnias.

Effective when used as directed against *Whiteflies, Aphids, Spider* and *Red Mites, Exposed Thrips, Lace Bugs, Japanese Beetles, Pavement Ants, Clover Mites* and *Armyworms*. When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Spray in one second bursts. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90°F (32°C). Over application may cause damage. Contact insects directly whenever possible. Retreat if infestation occurs, but not more than once every two weeks.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area away from [inaccessible to] children and pets and away from heat, sparks and open flame. Do not transport or store below 32°F (0°C). [Protect from freezing.] [Do not freeze.]

Pesticide Disposal and Container Handling: Do Not Puncture or Incinerate.

If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency [or 1-800-XXX-XXXX] for disposal instructions.

[Never place unused product down any indoor or outdoor drain.]

[This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label.]

[NOTICE:] To the extent consistent with applicable law, purchaser assumes all responsibility For safety and use not in accordance with directions.

L. Perrigo Company 515 Eastern Avenue Allegan, MI 49010